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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,716	01/28/2002	Kenji Asano	0230-0160P	3342

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EXAMINER

YAO, LEI

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,716

Applicant(s)

ASANO ET AL.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/24/01 & 7/26/04</u> | 6) <input checked="" type="checkbox"/> Other: <u>exhibit A</u> |

Art Unit: 1642

REQUEST FOR CONTINUED EXAMINATION

The request filed on 5/31/06 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09856716 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 1-4 are pending. Claims 3-4 have been cancelled. Claims 1-2 have been amended and are under consideration.

Previous final Office Action dated 12/20/05

The rejections in the previous Office action dated 12/20/05 including rejections of claims under 35 U.S.C. 102 and 103 are withdrawn. **If any rejection/objection is maintained, it will be stated again below.**

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 5/25/01, 7/26/04, and 3/10/05 are/is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New matter

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the claims 1-2 as newly amended claims recite "extract of *Lentinus edodes mycelium* in the absence of IL-2", which is not supported by instant specification. Instant specification as

*punctuation
grammar*

filed, provides a method of measuring the LAK cell with screening material and positive control with rIL-2 (page 12, line 25-29). However, the specification does not provide sufficient support for the instant claims reciting the *Lentinus edodes mycelium* in the absence of IL-2 in claims 1 and 2. The instant disclosure does not provide evidence that the screening material comprising *Lentinus edodes mycelium* does not contain IL-2 or does not induce IL-2 expression in the test condition. Therefore, the term "*Lentinus edodes mycelium* in the absence of IL-2" in the claims is not supported by instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Arinaga et al., (Int J Immunopharm. Vol 14, page 535-9, 1992) as evidenced by Mesh word search (exhibit A).

Claim 1 is drawn to a method for determining whether an extract of *Lentinus edodes mycelium* (LEM) has a Lymphocyte activated killing (LAK) activity-enhancing effect suitable for a subject comprising isolating cells, preparing a LAK-induced sample by treating lymphocyte with extract of *Lentinus edodes mycelium*, and measuring/comparing the activity of the LAK effect suitable for the subject.

Arinaga et al., disclose an *in vitro* method of determining enhancing a LAK activity by Lentinan, which is the major component of LEM as evidenced by Mesh word search (exhibit A) suitable for a subject. Arinaga et al., disclose the method comprising isolating lymphocytes and *in vitro* measuring/comparing cytotoxicity assay targeting a tumor cells (page 536, col 1). Arinaga et al., also disclose the LAK activity of isolated NK lymphocyte from the subject given Lentinan is significantly enhanced (page 527, table 2 and col 1).

Art Unit: 1642

2. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated Yamamoto et al., (Biosci Biotechnol Biochem, Vol 61, p 1909-12, 1997) as evidenced by Maeda et al., (the 3rd congress of the Federation of Asian and Oceanian Biochemists, 1982).

Claim 1 is set forth above. Claim 2 is further drawn to the method step of parathion of LEM in claim 1.

Yamamoto et al., disclose a method of cytotoxicity of lymphocytes, specifically NK cells, induced by a fraction of extract of *Lentinus edodes* mycelium (LEM). Yamamoto et al., disclose method steps, preparing fractions from extract of LEM based on sugar-cane bagasse, preparing NK lymphocytes, and measuring and comparing the LAK (page 1909-10, section materials and methods and result).

Yamamoto et al., refer a reference to further describe the details of preparing the extract of LEM as evidenced by Maeda et al. Yamamoto et al., disclose that extract of LEM has a LAK activity-enhancing effect and the LAK activity is increased further by fractions of extract of *Lentinus edodes* mycelium (page 1910-1911, and figure 1). Although Yamamoto et al., do not specific mention the LAK activity is suitable for the subject, it is inherent that the LAK activity enhanced by fraction of LEM would be suitable for the subject since the NK cells are freshly isolated from a spleen of a mouse and assay is using a mouse fibrosarcom as target cells.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER